

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/416,779 10/13/99 PREPARATA

F BUV-003.01

025181  
FOLEY, HOAG & ELIOT, LLP  
PATENT GROUP  
ONE POST OFFICE SQUARE  
BOSTON MA 02109

HM12/0523

EXAMINER

ZEMAN, M

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

05/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/416,779

Applicant(s)

PREPARATE ET AL.

Examiner

Mary Zeman

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 October 1999 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: *Notice to comply*.

Art Unit: 1631

### **DETAILED ACTION**

Applicant's election of Group II, claims 7-12, with traverse is acknowledged. Applicant's arguments with respect to claims 1-6 are persuasive, and these claims are rejoined with the elected claims. Claims 1-12 are examined herein.

#### ***Priority***

Applicant's claim to priority under 35 USC 119(e) to provisional applications 60/103,998, filed 10/13/98 and 60/125,704, filed 3/23/99, is acknowledged.

#### ***Information Disclosure Statement***

The information disclosure statement filed 8/22/00 has been considered. An initialed copy of the PTO-1449 is enclosed. Please note that while the International Search Report has been considered, it is lined through as it is not a published document, and therefore does not list a date of publication.

#### ***Drawings***

The drawings are objected to because in addition to the comments of the Draftsperson on the attached PTO-948, Figures 5 and 10 are impossible to read, and the meaning of the symbols and/or legends are not set forth in the Figure(s) or the Brief description of the Drawings. In Figures 2, 4 and 9, polynucleotide sequences which fall within the Sequence rules are recited, however, no unique sequence identifier is present in the figure(s) or the Brief Description of the drawings. Finally, Figures 7 and 8 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Correction is required.

Applicant is required to submit a proposed drawing correction in reply to this Office action. Formal correction of the noted defect can no longer be deferred until the application is allowed by the examiner.

#### ***Specification***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However,

Art Unit: 1631

this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

For example, Figures 2, 4 and 9, each disclose oligonucleotides of more than 10 nucleotides in length. Similarly on page 15, line 19 of the specification. Applicant should thoroughly review the specification to identify all instances of sequences falling within the sequence rules.

Applicant is requested to return a copy of the attached Notice to Comply with the reply.

#### ***Claim Objections***

Claim 1 is objected to because of the following informalities: the phrase "comprising sequence" should read "comprising a sequence". Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

Claims 4-6, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 4 and 5, is it the probes that are in an iterative pattern, or is it the universal and designate nucleotides within each probe that are in the iterative pattern?

Claim 10 is drawn to a chip of claim 8 "having a universal nucleotide..." Claim 6 similarly recites a set of probes "having a universal nucleotide..." This is confusing, as it is not clear whether there is only one universal nucleotide in the whole chip or set, or whether each probe must comprise at least one universal nucleotide.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1631

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Mirzabekov et al. (US 5,908,745).

The above rejected claims are drawn to isolated polynucleotides comprising designate and universal bases in an iterative pattern. The polynucleotides may comprise 2 fixed positions at the end of the probe. These polynucleotides can be in solution or displayed on a chip, for sequencing of DNA fragments. The universal polynucleotides can be 5-nitroindole or 3-nitropyrrole.

Mirzabekov et al. (US Patent 5,908,745) disclose isolated polynucleotides which comprise both designate and universal bases in iterative patterns. These polynucleotides can be displayed on a chip and used for sequencing. The preferred universal bases are 5-nitroindole and 3-nitropyrrole. An example of the iterative pattern of Mirzabekov et al. is set forth at column 5, lines 30-61, and in claims 17 and 19. Some sets of probes comprise at least two fixed positions at the end of the probe. The polynucleotides are synthesized in solution, then attached to a solid support, the sequencing chip. Therefore, this patent meets the limitations of the pending claims.

Claims 1 and 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 90/04652.

Claim 3 adds the limitation that two designate nucleotides be at the end of the pattern.

WO 90/04652 discloses oligonucleotides which have both designate (fixed) and universal (non-fixed) bases, in an iterative pattern (See pages 4-6 and Figure 1). A preferred universal base is deoxyinosine. Some of the oligonucleotides disclosed have two fixed positions at the end of the oligonucleotides.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Loakes et al. (1995).

Art Unit: 1631

Loakes et al. (Nucleic Acids Research, 1995, Vol. 23, No. 13, pages 2361-2366, Reference AI, PTO-1449) disclose polynucleotide probes which comprise universal and designate bases in iterative patterns. Table 1 shows examples of these patterns, especially probes 2, 6 and 9. These probes also have two fixed bases at the end of the probe- "CC". Therefore, the disclosure of Loakes et al. meets the limitations of the rejected claims.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergstrom et al (US 5,681,947).

Bergstrom et al. disclose oligonucleotides of at least 10 bases, wherein they comprise at least one universal base. A preferred universal base is 3-nitropyrrole. Table 1, primer 72 discloses the oligonucleotides which has 3-nitropyrrole in an iterative pattern, and has two designated bases at either end. Therefore, the disclosure of Bergstrom et al. meets the limitations of the rejected claims.

### *Conclusion*

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Floratos et al. (US 6,108,666) disclose methods of discovering patterns in sequences.

Drmanac et al. (US 5,972,619) disclose Sequencing by hybridization methods.

Fodor et al. (EP 834 575 A2) disclose sequencing, mapping and identification using oligonucleotide arrays.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

The fax number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose telephone number is (703) 305-3524.

mkz

May 18, 2001

  
MARY K. ZEMAN  
PATENT EXAMINER  
AV 1631

File copy

# NOTICE TO COMPLY WITH SEQUENCE RULES

Application No.

09/416,779

Examin r

Mary K Zeman

Applicant(s)

PREPARATA ET AL.

Art Unit

1631

## NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821-1.825 for the following reasons:

- ☒ 1. This application clearly fails to comply with the requirements of 37 CFR 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- ☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).
- ☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).
- ☐ 4. A copy of the "Sequence Listing in computer readable form has been submitted. However the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked up "Raw Sequence Listing".
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable. A Substitute computer readable form must be submitted as required by 37 CFR 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).
- ☐ 7. Other:

### Applicant must provide:

- ☒ An initial or ☐ A substitute computer readable form copy of the Sequence Listing.
- ☒ An initial or ☐ A Substitute paper copy of the Sequence Listing as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same, and, where applicable, include no new matter, as required by 37 CFR 1.821(e), (f), or (g) or 1.825(b) or (d).

### FOR QUESTIONS PLEASE CONTACT:

Rules Interpretation (703) 308-4216  
CRF Submission Help (703) 308 4212  
PatentIn software help (703) 308 6856

**PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE**